REMARKS

Claims 1-2, 6-11, 20, 23, and 24 are pending in the present application. With this response, claims 1, 6, 10, and 23 are amended, and claim 2 is canceled. Applicants reserve the right to pursue canceled subject matter in continuing applications. All claim amendments are made without prejudice and do not represent acquiescence in any ground of rejection.

Rejection under 35 U.S.C. § 112

Written Description Requirement

Claim 24 stands rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement. According to the office action, the specification lacks a description for the claimed method of protecting corneal cells against bacterial invasion and no working examples were provided for that claimed method. Applicants disagree with this rejection.

The specification adequately describes methods for protecting corneal cells against bacterial invasion such that those of skill in the art would understand that the Applicants were in possession of the full scope of the amended claims. A patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Applicants provide detailed protocols on pages 19-29 of the specification for practicing the invention. In paragraphs 0012-0019, 0023, 0025, 0054, 0104, and 0116-0117 of the specification, Applicants provide support for the use of surfactant protein-D as a protectant of corneal cells against bacterial invasion. While the office action suggests that the protective effects of surfactant protein-D are speculative, those protective effects are documented in the specification by way of Figures 1-7 (paragraphs 0012-0018) and Example 4 (paragraphs 0116-0017). There is no suggestion that the beneficial aspects of the invention would not be observed when employed prophylactically, and the office action does not provide any basis for a presumption against the claimed protective effects. Furthermore, those of ordinary skill in the art would understand that the term "reduction" may encompass a reduction in invasion both at the instant of bacterial exposure, as would occur with protective use, and following bacterial

exposure. Paragraph 0053 provides that, by definition, "treating" or "treatment" include "preventing the onset of symptoms," and thus preventative treatment is included within the scope of the claims. Moreover, the term "protection" does not necessarily imply a complete absence of invasion. Rather, a reduction in invasion is consistent with both full and partial protection against invasion. Therefore, Applicants submit that the specification adequately describes the methods for use of surfactant protein-D as a corneal cell protectant.

The specification provides sufficient working examples such that those of ordinary skill in the art would understand that Applicants had possession of the invention as claimed. Applicants provide ample support in Figures 1-7 (paragraphs 0012-0018) and Example 4 (paragraphs 0116-0117) to demonstrate the protective effects of surfactant protein-D against bacterial invasion of corneal cells *in vitro*. Although the office action mentions that no *in vivo* data is provided to demonstrate the protective properties of surfactant protein-D, Applicants submit that *in vivo* examples are not required for patentability. In this regard, M.P.E.P. § 2164.02 states that: "based upon the relevant evidence as a whole, there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence." *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). Because the *in vitro* and *in vivo* models are properly correlated and one of ordinary skill in the art would expect the same protective effects to be observed *in vivo* as observed *in vitro*, there is no requirement for *in vivo* working examples. In light of the detailed description demonstrating the protective effects of tear surfactant proteins by way of examples and figures, those of ordinary skill in the art would understand that Applicants were in possession of the full scope of claimed protective methods. Accordingly, Claim 24 is adequately described, and reconsideration and withdrawal of the rejection is requested.

Enablement Requirement

Claims 1 and 6-11 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification. According to the office action, the specification does not enable those of skill in the art to practice the claimed invention without undue experimentation. The office action suggests that Claims 2 and 23 would be allowable if

rewritten in independent form. Although Applicants believe that the full scope of the claims is enabled, solely to expedite prosecution, Applicants are amending the claims to recite that a therapeutically effective amount of a tear surfactant protein is used to treat an ocular disease. To the extent the rejection applies to the claims as amended, Applicants respectfully traverse and request reconsideration because there is no evidence of record suggesting that a skilled practitioner would be unable to carry out the claimed methods.

Claim 24 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification. According to the office action, the specification does not enable one of ordinary skill in the art to practice the claimed methods of protecting corneal cells against bacterial invasion, and the full scope of Claim 24 is not enabled. Applicants disagree with this rejection.

Applicants submit that Claim 24 is enabled because those of ordinary skill in the art could practice the claimed invention without undue experimentation. In this regard, M.P.E.P. § 2164.08 states that: "not everything necessary to practice the invention need be disclosed." In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). The methods described on pages 19-29 and in Example 4 (paragraphs 0116-0117) of the specification enable those of ordinary skill in the art to practice the invention both preventatively and following infection. Moreover, the methods on pages 25-29 describe practicing the invention with contact lenses, a use that would encompass the protective aspects of the invention. While the methods for protecting corneal cells from bacterial invasion are demonstrated only *in vitro*, those of ordinary skill in the art could readily translate those methods to *in vivo* applications. In fact, paragraphs 0084 and 0085 suggest a means for adapting the studies to *in vivo* applications. The only requirement for enablement is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Because the specification teaches those of ordinary skill in the art to practice the protective aspects of the invention, the enablement requirement is satisfied for Claim 24.

Applicants submit that the full scope of Claim 24 is enabled by the specification. In this regard, M.P.E.P. § 2164.08 states that: "the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Claim 24 is drawn to the protective effects of surfactant

protein-D in corneal cells and the specification provides examples and protocols for practicing the invention with each of those elements. While only a reasonable correlation in scope is required, Applicants have described methods having a high correlation in scope with Claim 24. While the examiner suggests that the *in vitro* examples, including Example 4 (paragraphs 0116-0117), do not enable practice of the invention *in vivo*, there is no requirement that the specification provide *in vivo* examples. Moreover, M.P.E.P. § 2164.02 states that: "since the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of lack of correlation for an *in vitro* or *in vivo* animal model example." Although the office action suggests that the *in vitro* model does not enable practice of the invention *in vivo*, it does not provide any reason for a lack of correlation between the two systems. Therefore, the examiner has not met the initial burden for the enablement rejection.

For the foregoing reasons, the specification enables those of ordinary skill in the art to practice the protective aspects of the invention as set forth in Claim 24 without undue experimentation, and the full scope of Claim 24 is enabled by the specification. Accordingly, Claim 24 is adequately enabled, and reconsideration and withdrawal of the rejection is requested.

Conclusion

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants respectfully submit that the present application is in condition for allowance. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Favorable consideration and an early notice of allowance are respectfully requested.

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